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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,092	07/12/2007	Kirk Knowlton	ST-UCSD3120-1	7890

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,092	KNOWLTON ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/09 & 2/2/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-6,14-19,27 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13,20-26,28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

APPLICANT'S ARGUMENTS

1. Applicant's invention is directed to in vivo and in vitro methods of detecting enteroviral infections as set forth in independent claims 1 and 7. In addition, the instant invention discloses kits comprising a labeled dystrophin epitope-specific antibody or Fab fragment thereof as set forth in independent claims 14 and 20.

Note: Claims 1-30 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election without traverse of Group II (claims 1-6, 14-19, 27, and 29) in the reply filed on 10/27/09 is acknowledged. Thus, the rejection is deemed proper and is made FINAL.

WITHDRAWN CLAIMS

3. Claims 1-6, 14-19, 27, and 29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 REJECTIONS

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7-13, and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9, 12, and 13: The claims as written are ambiguous because it is unclear what dystrophin cleavage product Applicant is detecting in

independent claim 7. Since claims 8, 9, 12, and 13 depend on independent claim 7, those claims are vague and indefinite as well.

Claims 20-24: The claims as written are ambiguous because in independent claim 20, the intended use of the kit and how the detection of the dystrophin cleavage product is disclosed. As a result, claims 21-24 that depend on claim 20 are indefinite because they contain limitations directed to the intended use and how the dystrophin cleavage product is detected. Hence, the claims are not further limiting.

Claims 7-13: The claims as written are ambiguous because it is unclear what assay(s) Applicant is claiming that is/are claiming to be compatible with the instant invention. Please clarify in order that one may readily ascertain what is being claimed.

102/103 REJECTION

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-26, 28, and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Campbell et al (US Patent No. 5,308,752).

Campbell et al disclose the diagnosis of autosomal muscular dystrophy. The diagnostic method involves using antibodies reactive with components of the dystrophin-glycoprotein complex (see entire document, especially, abstract). The dystrophin-glycoprotein complex may be isolated as an intact complex with

lectins that bind to the glycoprotein components of the complex. The lectins are typically coupled to a solid support such as agarose (column 2, lines 25-49). One diagnostic method involves testing for the presence of the components of the dystrophin-glycoprotein complex and using immunofluorescent techniques (column 6, lines 16-33). In still another embodiments, the diagnostic method involves antibodies specifically reactive with an extracellular components of the dystrophin-glycoprotein complex are labeled with a detectable reporter group and administered to a subject and analyzed using conventional immunodiagnostic methods (columns 6-7, bridging paragraph). Various antibodies to dystrophin-associated proteins were analyzed (column 19, lines 1-28). Thus, both Applicant and Campbell et al disclose a detectably labeled dystrophin epitope-specific antibody/Fab fragment.

While Campbell et al does not specifically state that a kit having the detectably labeled dystrophin-glycoprotein complex, a kit containing the component is inherent because of the ever present need for such kits in hospitals, clinics, or other medical facilities and the fact that Campbell et al disclose a step-by-step procedure of performing the diagnostic method (i.e., column 4-5, bridging paragraph; column 5, lines 17 – column 6, line 63; columns 6-7, bridging paragraph). Furthermore, it is noted that the claims disclose the intended use of the labeled dystrophin complex. Applicant is reminded that the composition/product of the prior art is the same/similar as that being claimed by Applicant. Although the cited prior art does not disclose the particular use, the composition/product would be capable of having the same use as Applicant's

invention since a composition/product and its properties are inseparable. Thus, Applicant's composition/product, like the cited prior art, would be 'capable of' performing the same function.

SPECIFICATION

10. The disclosure is objected to because of the following informalities: Applicant is respectfully requested to incorporate the continuing data into the first paragraph of the specification.

Appropriate correction is required.

COMMENTS/NOTES

11. It should be noted that no prior art has been cited against the in vitro method of detecting enteroviral infection (independent claim 7); however, Applicant MUST address and overcome the 112 rejections.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

November 25, 2009